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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,837	09/09/2003	Mark A. Reiley	9448.17205-CIP DIV 6	1759
21971	7590	07/28/2005	EXAMINER	
WILSON SONSINI GOODRICH & ROSATI			ISABELLA, DAVID J	
650 PAGE MILL ROAD			ART UNIT	
PALO ALTO, CA 94304-1050			PAPER NUMBER	

3738

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/657,837

Applicant(s)

REILEY, MARK A.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 5/9/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7, 10 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8, 9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                                    |

***Status of the Claims***

Claims 3,7,10, 20-22 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species. Applicant's amendment filed on 5/9/2005 includes amendment solely to claim 1.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,4-6,12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (6132464).

Martin discloses a prosthesis to replace all or a portion of a natural facet joint on a vertebral body comprising: a fastening element adapted to be installed within the vertebral body at or near a pedicle and without support by a lamina and an artificial facet joint structure carried by the fastening element adapted and configured to replace all or a portion of a natural facet joint. See figure 5 where the fastening element is the screw 18 and the facet joint structure are elements 1,2,11 and 16.

Claims 2,4,5,6 the facet joint is mechanically and removably affixed to the fastening element as broadly worded.

Claim 12, as broadly worded the facet joint structure is connected to the fastening element in such a manner that it can pivot with respect thereto.

Claims 13-17, the claimed features are fully disclosed by Martin.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8,9,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin as applied to claim 1 above, and further in view of Kaute (3596656).

Kaute teaches the use of a polymer washer that is inserted between the body of the implant and the head of the fastening element. The washer is formed of a material that will not scratch the outer metallic surfaces of the fastening element and the body of the implant. The washer prevents slight misalignment between the fastening element and the axis of the bore of the implant to provide firm engagement therebetween. Additionally, the washer allows the fastening element and the implant to be constructed from dissimilar metals without creating an electrolytic reaction between the parts. To use a washer between the implant and fastening element of Martin to allow for firm engagement therebetween would have been obvious from the teachings of Kaute.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin as applied to claim 1 above, and further in view of Karpman et al (6214012).

Karpman et al teaches the combination of a screw type fastening element with means for dispensing cement to aid in the affixing of the screw to the affected tissues. (see figure 10). If the deterioration of the spinal tissue requires additional support for anchoring an implant thereto with the use of a threaded fastening element, one could look to the device of Karpman et al to provide both the threaded anchoring and the means to augmenting the fixation to the weakened spinal tissue with the use of cement.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin as applied to claim 1 above, and further in view of Eitenmuller et al (5108399).

The use of a coating of bony in growth material on a threaded fastening element to provide better fixation and stabilization of the fastening element to the adjacent tissue is taught by Eitenmuller. To provide a bioactive coating on the fastening element of Martin to ensure full fixation of the fastening element to the adjacent tissues would have been obvious to one with ordinary skill in the art from the teachings of Eitenmuller.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
7/21/2005